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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,694

09/11/2006

Michel Quoniam

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SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
SUITE 800  
WASHINGTON, DC 20037

EXAMINER

CHU, KING M

ART UNIT

PAPER NUMBER

3788

NOTIFICATION DATE

DELIVERY MODE

01/06/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
USPTO@SUGHRUE.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,694	<b>Applicant(s)</b> QUONIAM, MICHEL	
	<b>Examiner</b> KING M. CHU	<b>Art Unit</b> 3788	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/2010 has been entered.

### **Claim Rejections - 35 USC § 103**

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 4, 7-9, 11, 13, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (Young 2003/0172927) in view of Razeti (2003/0108714).

#### In reference to Claim 1

Young discloses a blister strip (150) for use in a fluid or powder inhaler, and including a plurality of blisters (see Figure 11, 160), each formed by a reservoir (formed by 160) including an opening (between 160 and 152 at the rim of 160) that is sealed in leaktight manner by a tearable layer (158), wherein the blister strip comprises at least a base layer (154), and a cavity layer (152) that is provided with cavities forming the blister walls (walls of 160), wherein the blisters contain a pharmaceutical powder (162); and the opening is opened in a clean and

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accurate manner without any residual portions of the tearable layer on the edges of the opening (see Figures 11-13 where there are no residual portions of the tearable layer on the edge of the opening).

Young discloses the claimed invention as discussed above with the exception of the following claimed limitations that are taught by Razeti: a base layer (19) that is provided with openings (23, Figure 5) forming the openings of the blisters, and said tearable layer (158, of Young see above) comprising a first tearable-layer portion (21) that is disposed between said base layer (19) and said cavity layer (152 of Young), and a second tearable-layer portion (22) that is disposed on the opposite side of said base layer, said first and second tearable-layer portions being connected together at each opening of the base portion (see figures 4 and 5, where the first and second tearable layers (21 and 22 are connected at 23 and 24); wherein the connection between the first tearable-layer portion and the second tearable-layer portion is provided all around the opening (see Figure 5 where 21 and 22 that are attached to 11 are provided all around the openings 23 and 24), such that the opening is opened in a clean and accurate manner without any residual portions of the tearable layer on the edges of the opening (see Figure 5 where the where 21 and 22 that is attached to 11 does not leave any residual portions on the edges of the opening).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti so that the base layer of Young is replaced with the base layer of Razeti as well as provide the first and second tearable-layer portions of Razeti outlined above. Razeti is relevant art since one of ordinary skill in the art at the time the invention was made would have looked to other multi-layered film sheets and peel-off methods for lids that

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were known in the art thus provided sufficient motivation for combination and making the container opening operations convenient for users, as taught by Razeti and (column 1, paragraphs 0011).

In reference to Claim 3

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 and Razeti further teaches that the first and second tearable-layer portions are connected together as a single part in each opening of the base layer (see Figure 5, where 21 and 22 are connected as a single part).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti for reasons stated in claim 1.

In reference to Claim 4

Young in view of Razeti discloses the claimed invention as discussed above for claim 3 and Razeti further teaches that the single-part connection is made by fusing material (21 and 22 are fused together since 22 is a hot-extruded polythene which fuses to 21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti for reasons stated in claim 3.

In reference to Claim 7

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations: the first and second tearable-layer portions comprises a film having thickness that is less than 100  $\mu\text{m}$ , advantageously lying in the range 10  $\mu\text{m}$  to 40  $\mu\text{m}$ , and preferably equal to 30  $\mu\text{m}$ .

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However Razeti discloses that the second tearable layer 22 is between 12 and 15 microns, and 21 is 30-40 microns, see col. 3, paragraph 0033-0037). Furthermore it has been held that the thickness of the tearable layers of a claim were disclosed in the prior art (Razeti), it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955).

In reference to Claim 8

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 and Razeti further teaches that the base layer (19) comprises polyester (col. 3, paragraph 0028). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti so that the base layer of Young is modified to have polyester as one of the material of choice since the selection of a known material based on its suitability for its intended purpose was an obvious extension of prior art, In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

In reference to Claim 9

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations: the base layer comprises a film having thickness that is less than 100  $\mu\text{m}$ , advantageously lying in the range 40  $\mu\text{m}$  to 60  $\mu\text{m}$ , and preferably equal to 50  $\mu\text{m}$ .

However Razeti discloses that the base layer (19) is 12 microns, see col. 3, paragraph 0033). Furthermore it has been held that the thickness of the base layer of a claim were disclosed in the prior art (Razeti), it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955).

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In reference to Claim 11

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 and Razeti further teaches: the tearable layer further includes a first aluminum layer (12) that is fastened (via 14 and 15) to said second tearable layer portion (22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti so that an aluminum layer is fastened to the second tearable layer portion in order to provide an assured barrier against contaminations of the product, as taught by Razeti (col. 1 paragraph 0012).

In reference to Claim 13

Young in view of Razeti discloses the claimed invention as discussed above for claim 13 and Razeti further discloses that a polyester layer (15) and an adhesive layer (14) are disposed between said second tearable-layer portion and said first aluminum layer (see Figures 4 and 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti so that a polyester layer and an adhesive layer are disposed between the second tearable-layer portion and the first aluminum layer in order to make the container opening operations convenient for users, as taught by Razeti and (column 1, paragraphs 0011).

In reference to Claim 20

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 and Young further teaches a dry-powder inhaler (20) comprising the blister strip according to claim 1 (see Rejection of claim 1).

In reference to Claim 21

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Young discloses a blister strip (12) for use in a fluid or powder inhaler, comprising: a blister (see Figure 11, 160) formed by a reservoir (formed by 160) comprising a blister opening (between 160 and 152 at the rim of 160); a first tearable layer (158) sealing the blister opening (see Figures 11 and 12), where in the blister contains a pharmaceutical powder (162).

Young teaches the claimed invention as discussed above with the exception of the following claimed limitations that are taught by Razeti: a base layer (19) above the first tearable layer (the first tearable layer 158 of Young is replaced with 21 of Razeti) and comprising a base layer opening (23) corresponding to the blister opening (container opening 24); a second tearable layer (22) above the base layer and connected to the first tearable by a material connection (see Figure 5, 21 and 22) passing through the base layer opening so that, upon lifting the second tearable layer (22), an edge of the base layer opening tears the material connection formed between the first tearable layer and the second tearable layer (see figure 5 where lifting 22 tears the material connection formed at the opening), thereby unsealing the blister opening (see Figure 5); and wherein the connection between the first tearable layer and the second tearable layer is provided all around the blister opening (see Figure 5 where 21 and 22 that are attached to 11 are provided all around the openings 23 and 24).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti so that the tearable layer in Young is modified with features of Young outlined above, in order to make the container opening operations convenient for users, as taught by Razeti (column 1, paragraphs 0011).

In reference to Claim 22



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Young in view of Razeti discloses the claimed invention as discussed above for claim 21 and Razeti teaches that the first tearable layer and the second tearable layer is part of an integral one-piece construction made from a single structural piece (in as much as applicant has claimed the integral one-piece construction made from a single structural piece, Figure 5 of Razeti shows 21 and 22 forming the claimed structure).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti so that the first and second tearable layers are part of an integral one-piece construction made from a single structure piece in order to make the container opening operations convenient for users, as taught by Razeti (column 1, paragraphs 0011).

In reference to Claim 23

Young discloses a blister strip (150) for use in a fluid or powder inhaler, comprising: a plurality of blisters (see Figure 11, 160), each formed by a reservoir (formed by 160) including an opening (between 160 and 152 at the rim of 160);, a cavity layer (152) having blister walls which define the reservoirs (walls of 160); a base layer (154), a tearable layer (158) that seals the blister openings in leaktight manner.

Young discloses the claimed invention as discussed above with the exception of the following claimed limitations that are taught by Razeti: a base layer (19) that is provided with openings (23 and 24, Figure 5) forming the openings of the blisters, and said tearable layer (158, of Young see above) comprising a first tearable-layer portion (21) that is disposed between said base layer (19) and said cavity layer (152 of Young), and a second tearable-layer portion (22) that is disposed on the opposite side of said base layer, said first and second tearable-layer portion that is disposed on an opposite side of said base layer (see figures 4 and 5, where the first

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and second tearable layers (21 and 22 are connected at 23 and 24); said first and second tearable-layer portions being connected together by connection portions (21 and 22 in the opening 23 and 24, Figure 5) disposed in the openings of the base portion (see Figure 5 where 21 and 22 that are attached to 11 are provided in the openings 23 and 24).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti so that the base layer of Young is replaced with the base layer of Razeti as well as provide the first and second tearable-layer portions of Razeti outlined above. One of ordinary skill in the art at the time the invention was made would have looked to other multi-layered film sheets and peel-off methods for lids that were known in the art thus provided sufficient motivation for combination and making the container opening operations convenient for users, as taught by Razeti and (column 1, paragraphs 0011).

In reference to Claim 24

Young in view of Razeti discloses the claimed invention as discussed above for claim 23 and Razeti further teaches that upon lifting of the tearable layer off one of the blisters (22), an edge of the opening of the base layer (see edge of 19 at 23 in Figure 5 which causes the connection portion 22 and 21 to separate from the first tearable-layer portion) causes the connection portion to separate from the first tearable-layer portion, thereby opening the reservoir of the blister.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti so that the base layer of Young is replaced with the base layer of Razeti as well as provide the first and second tearable-layer portions of Razeti outlined above. One of ordinary skill in the art at the time the invention was made would have looked to

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other multi-layered film sheets and peel-off methods for lids that were known in the art thus provided sufficient motivation for combination and making the container opening operations convenient for users, as taught by Razeti and (column 1, paragraphs 0011).

4. Claims 5-6, 10, 12, 15-16, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (Young 2003/0172927) in view of Razeti (2003/0108714) and further in view of Fuller et al. (Fuller 2002/0008046).

In reference to Claim 5

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations that are taught by Fuller: the tearable layer comprises polyethylene (Fuller teaches that polyethylene was a common material used in known blister packs, col. 3, paragraph 0023-0024).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti and Fuller to use polyethylene as a material of choice for the tearable layer since the selection of a known material based on its suitability for its intended purpose was an obvious extension of prior art, In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Further more Fuller provided motivation for the combination in order to provide a strong material for enclosing medication or pills, as taught by Fuller (col. 1, paragraph 0002).

In reference to Claim 6

Young in view of Razeti discloses the claimed invention as discussed above for claim 1, that the said first and second tearable-layer portions are constituted by a continuous film (since 22 is joined to 21, 21 and 22 are considered to be a continuous film), with the exception of the following claimed limitations that are taught by Fuller: the tearable layer is polyethylene (Fuller

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teaches that polyethylene was a common material used in known blister packs, col. 3, paragraph 0023-0024).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti and Fuller so that the first and second tearable-layer portions are a continuous film in order to provide a strong material for enclosing medication or pills, as taught by Fuller (col. 1, paragraph 0002).

In reference to Claim 10

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations that are taught by Fuller: the cavity layer comprises polyethylene and/or polypropylene (Fuller teaches that polyethylene and polypropylene were a common material used in known blister packs, col. 3, paragraph 0023-0024).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti and Fuller to use polyethylene as a material of choice for the cavity layer since the selection of a known material based on its suitability for its intended purpose was an obvious extension of prior art, *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Further more Fuller provided motivation for the combination in order to provide a strong material for enclosing medication or pills, as taught by Fuller (col. 1, paragraph 0002).

In reference to Claim 12

Young in view of Razeti discloses the claimed invention as discussed above for claim 11 with the exception of the following claimed limitations: the first aluminum layer has thickness

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that is less than 50  $\mu\text{m}$ , advantageously lying in the range 10  $\mu\text{m}$  to 30  $\mu\text{m}$ , and preferably equal to 20  $\mu\text{m}$ .

Fuller teaches an aluminum foil that had a thickness of 0.0008 inch which is approximately equal to 20.32 microns (see col 3, paragraph 0025).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti and Fuller so that a specific thickness is provided in order to provide a strong material for enclosing medication or pills, as taught by Fuller (col. 1, paragraph 0002). Further, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In reference to Claim 15

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations that are taught by Fuller: the cavity layer further includes a second aluminum layer (Fuller teaches that it was well known in the art at the time of the invention to use an aluminum foil to be attached to the blister sheet to provide strength as well as provide a backing layer, col. 1 paragraph 0004).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti and further in view of Fuller in order to provide an additional aluminum layer to the cavity layer in order to provide a strong material for enclosing medication or pills, as taught by Fuller (col. 1, paragraph 0002).

In reference to Claim 16

Young in view of Razeti and Fuller discloses the claimed invention as discussed above for claim 15 with the exception of the following claimed limitations: a polyester layer and an

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adhesive layer are disposed between said cavity layer and said second aluminum layer.

However Razeti does teach a polyester layer (15) and an adhesive layer (14) disposed between an aluminum layer (12) and another layer (22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti and Fuller to provide the same layering to the cavity layer in order to assure barrier against contaminations of the product contained in the container, as taught by Razeti (col. 1, paragraph 0012).

In reference to Claim 18

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 and Razeti further teaches the a strength of the adherence of the tearable layer to the base layer between the openings is different from a strength of the adherence in the proximity of said openings (see Figures 4 and 5 where layers 21 is not adhered to the base layer 19 at the proximity of the opening, therefore the strength of the adherence is different and in Figure 5 the strength of the tearable layer 21 and 22 is adhered stronger to each other than to the proximity of the opening 24 and 23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti for reasons stated in claim 1.

In reference to Claim 19

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 and Young further teaches that the blisters contain a pharmaceutical powder (162).

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Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (Young 2003/0172927) in view of Razeti (2003/0108714) and further in view of Lippert (4,938,414).

In reference to Claim 14

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations that are taught by Lippert: the tearable layer includes a first outer layer, preferably formed by a printer's varnish (Lippert teaches that a printer's varnish maybe applied to the face of sheets, where the printer's varnish in itself is a layer).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti and Lippert so that a first outer layer formed by a printer's varnish is provided in order to provide an advertisement, as taught by Lippert (col. 3, lines 24-26).

In reference to Claim 17

Young in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations: the cavity layer includes a second outer layer, preferably formed by a protective layer or by a layer of varnish (Lippert teaches that a printer's varnish maybe applied to the face of sheets, where the printer's varnish in itself is a layer).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Young in view of Razeti and Lippert so that a second outer layer is provided in order to provide advertisement, as taught by Lippert (col. 3, lines 24-26).

### **Response to Arguments**

5. Applicant's arguments, see Remarks, filed 11/19/2010, with respect to the rejection(s) of claim(s) 1-22 under the primary reference Ekelius US 6,637,431 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Young et al. (Young 2003/0172927).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KING M. CHU whose telephone number is (571)270-7428. The examiner can normally be reached on Monday - Friday 9AM - 6PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on (517)272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/J. Gregory Pickett/  
Primary Examiner, Art Unit 3728

/KING M CHU/  
Examiner, Art Unit 3788